OKLAHOMA STATE BOARD OF OSTEOPATHIC EXAMINERS

OKLAHOMA PROPER PRESCRIBING

DISCLOSURE NOTICE

- No conflicts to disclose
- Employed by State of Oklahoma.

OBJECTIVES

- Learn the requirements of Oklahoma Osteopathic Physicians when prescribing controlled drugs.
- Learn how the State Board of Osteopathic Board approaches investigations involving controlled drugs.
- Learn the "red flags" that the Sate Board of Osteopathic Board looks at when reviewing physician's prescribing practices.

Oklahoma State Board of Osteopathic Examiners *Established 1921*

Michael T. Leake Jr., J.D. – Executive Director



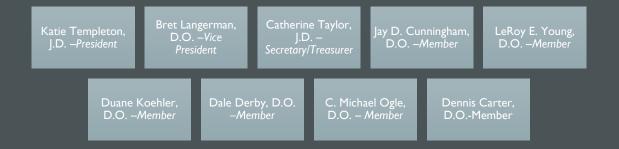


STAFF

- Michael Leake, J.D., Executive Director
- Richard Zimmer, CMBI, Chief Investigator
- John Mobley, CMBI, Investigator
- Christi Aquino, Director of Licensing
- Kelsey Devinney, Business Manager
- Kimberly Contreras, Investigative Assistant
- Janis Womack, Administrative Technician II
- Daniel Gamino, J.D. General Counsel (Contractor)
- Patrick Quillian, J.D. Special Prosecutor (Contractor)



CURRENT BOARD MEMBERS





INVESTIGATION & PROSECUTION OF (IM)PROPER PRESCRIBING

ALL HEALTH OVERSIGHT AGENCIES ARE ESTABLISHED BY LAW AND SHARE ONE COMMON MISSION: **TO PROTECT THE PUBLIC.**

HOW DO WE PROTECT THE PUBLIC, AND THE OSTEOPATHIC PROFESSION, FROM THE UNETHICAL PRACTITIONER?

- State and Federal Statutes
- State Administrative Rules & Regulations
- Enforcement
- Screening and Licensing qualified applicants
- Educate



OBNDD PRESCRIBING RULES OAC TITLE 475

- Only a <u>registered practitioner</u> may issue a <u>prescription for a</u> <u>Schedule II, III, IV and V</u> Controlled Dangerous Substance (CDS)
- It is the **responsibility of the registered practitioner** to guard against diversion of CDS by authorized employees
- A prescription for a CDS must be issued for a <u>legitimate medical</u> <u>purpose</u> by a registered practitioner
- A prescription may not be issued for a CDS to a drug dependent person for the purpose of continuing his/her dependence on such drugs

DEA TITLE 21 CODE OF FEDERAL REGULATIONS (CFR)

1301.71 Security Requirements Generally

• All applicants and registrants shall provide effective controls and procedures to guard against ... diversion of controlled substances

1301.76 Other Security Controls for Practitioners

 The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances

SENATE BILLS 1446 & 848

- Excluded: SB 1446 & 848 do not apply to patients receiving active treatment for <u>cancer</u>, <u>hospital</u>, <u>palliative care</u>, <u>residents of long-term care</u> <u>facility</u>, or medication for <u>treatment of substance abuse or opioid</u> <u>dependence</u>.
- CMES: All Oklahoma physicians (DOs/MDs) who hold an OBN and DEA registration must take one (1) hour of Proper Prescribing every single year. The one (1) course must be approved by the DO Board or it will not count—see the Agency's website for all approved courses.
- PMP: All Oklahoma physicians (DOs/MDs) are required to check the PMP at the time of the initial prescription for opioids, synthetic opioids, semisynthetic opioids, benzos, and carisoprodol and then at least every 180 days. You must document that your checked PMP—you may include a copy of the PMP in the record (but this is not required).
 - It is recommended, but not required, that you check PMP every time you order a CDS.
- <u>MME</u>: If you choose to prescribe greater than 100 MME, it is very important that the patient's records clearly show documentation for your rationale.

SENATE BILLS 1446 & 848 PATIENT-PROVIDER AGREEMENT & WRITTEN POLICIES

- Pain Management Agreement: Practitioner shall enter into an Agreement with a patient: (1) at the time of the third prescription for opioid drug; (2) if the patient requires more than three months of pain management; (3) if the patient is receiving benzos and opioids together (even if it is only a one-time script); (4) if the patient requires more than 100 MMEs; (5) the patient is pregnant; or (6) with the parent or legal guardian if patient is a minor.
- Written Policies: Any provider authorize to prescribe opioids shall adopt and maintain a written policy including execution of written contract between practitioner and a "qualifying opioid therapy patient."
 - "Qualifying Opioid Therapy Patient": (1) a patient requiring opioid therapy for more than three (3) months; (2) a patient who is prescribed benzos and opioids together (even it if is only one time); or (3) a patient who is prescribed a dose that exceeds 100 MMEs.

SENATE BILLS 1446 & 848 INITIAL SCRIPT & INFORMED CONSENT

- Prior to Initial Script: Practitioner shall: (1) take and document a thorough medical history; (2) conduct and document a physical exam; (3) develop a treatment plan; (4) access the PMP; (5) limit supply to no more than seven (7) days for acute pain; and (6) if patient is under the age of eighteen (18), enter into a Patient-Provider Agreement with the parent or legal guardian.
- Informed Consent: Prior to initial prescription and again prior to third prescription, practitioner must discuss risk including: (1) risk of addiction and overdose, dangerous of taking opioids with alcohol, benzos, and other CNS depressants; (2) reason the prescription is necessary; (3) alternative treatment available; and that (4) risks can include fatal respiratory depression. Practitioner shall document in the patient's record each time that the informed consent discussion occurs.

SENATE BILLS 1446 & 848 ACUTE vs. CHRONIC

Acute	Chronic
 <u>Shall not</u> issue an initial prescription for an opioid drug in a quantity that exceeds seven (7) day supply. <u>Shall</u> be for the lowest effective dose of immediate-release opioid drug <u>Must</u> state "acute pain" on face of Rx. Following initial seven (7) day script, and after an in-person or by telemedicine, a second seven (7) days script may be ordered by the provider if: (1) it is determined the script is necessary/appropriate, rationale is documented, and a determination (with documentation) is made that additional script does not present undue risk of abuse, addiction or diversion. 	 If continuing opioid treatment for three (3) months or longer, provider shall: (1) review every three (3) months course of treatment, any new information regarding etiology of pain, and the progress toward treatment objectives; (2) assess patient prior to every renewal to determine if patient is experiencing dependency and document assessment; (3) periodically make reasonable efforts, unless clinically contraindicated to stop, decrease dosage or try other treatment modalities; (4) review PMP; (5) monitor compliance with patient provider agreement; and (6) state "chronic pain" on the face of the script. After one (1) year of compliance with provider agreement, the physician may review treatment plan and assess patient at six (6) month intervals. Assessment may be performed by a mid-level providers (PA/APRN). Face-to-face assessment is recommended by not required; however, an in-person visit is required to start a CDS.

STATE STATUTES, RULES, AND REGULATIONS

- The Oklahoma Osteopathic Medicine Act
 - Oklahoma Statute (O.S) Title 59
 - Sections 626 (3) (D), 637 (A) (2) (g) (3)
- OAC Title 510 State Board of Osteopathic Examiners
 - Subchapter 9. Prescribing for Chronic Pain
 - Requirements for osteopathic physicians who prescribe for chronic, intractable pain

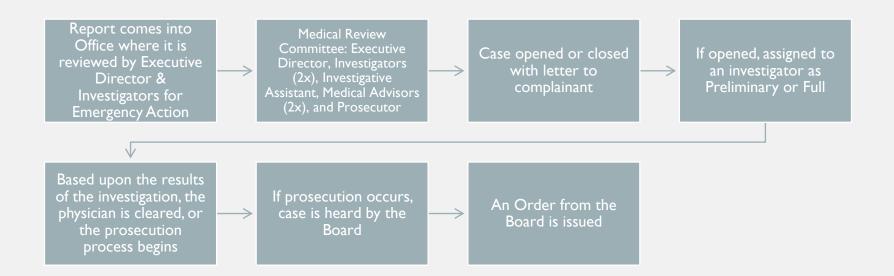
(visit our website – www.osboe.ok.gov)

THE STATUTE (LAW) – TITLE 59 WHAT DOES IT SAY?

- ... Investigators may investigate and inspect the records
- ... To ensure compliance with any State of Federal law or rule affecting the practice of osteopathic medicine
- ... Licensee shall be deemed to have given consent

Refusal to allow such access, entry, or inspection may constitute grounds for non-renewal, suspension or revocation of license. <u>Refusal</u> will guarantee a visit before the Board for non-compliance.

THE PROCESS



WHAT INITIATES AN INVESTIGATION BY THE BOARD?

- Complaints from the public
- Other physicians
- Family members of patients
- Pharmacists
- Citizens of a community
- Oklahoma Attorney General
- Oklahoma Bureau of Narcotics
- Drug Enforcement Administration

MEDICAL REVIEW COMMITTEE

Consists of:

- Executive Director
- Prosecuting Attorney
- Investigators (x2)
- Investigation Assistant
- Medical Advisors (x2)

Review Complaints for:

- Violation of Oklahoma Osteopathic Medicine Act
- Violation of OAC 510- State Board of Osteopathic Examiners
- Violation of other State or Federal Law especially violation of OBN or DEA Statutes/Rules

Possible Outcomes:

 No Jurisdiction, No Clear and Convincing Evidence, No Violation, Independent Medical Judgement, Premlinary Investigation, Full Investigation

PREMLINARY CONSIDERATIONS

During the investigation

- Volume > CDS dosage units per month, year
- Number CDS scripts per day
- Class of CDS / combination of CDS "cocktails"
- Ignoring or failing to check PMP
- Patient Deaths
- MME Morphine Milligram Equivalents

RED FLAGS FOR INVESTIGATORS

- Patients come from everywhere
- Multiple drug stores used to fill prescriptions
- Multiple prescriptions to single patient
- Poor medical chart/records
- Excessive patient count
- Early Refills



RED FLAGS FOR INVESTIGATORS, CONT'D

- High number of RX per month
- High number of dosage units per month
- Multiple prescribers for same patient
- Friends and Family receiving same CDS RX
- Multiple Overdose deaths
- Cash payments
- Excessive MME Number (100+)





THE VIOLATIONS

59 O.S. § 637 (A)

59 O.S. § 637 (A)

- **§59-637.** Refusal to issue or reinstate, suspension or revocation of license Hearing, witnesses and evidence Judicial review.
- A. The State Board of Osteopathic Examiners may refuse to admit a person to an examination or may refuse to issue or reinstate or may suspend or revoke any license issued or reinstated by the Board upon proof that the applicant or holder of such a license:
- 1. Has <u>obtained a license</u>, license renewal or authorization to sit for an examination, as the case may be, <u>through fraud</u>, <u>deception</u>, <u>misrepresentation or bribery</u>; or has been granted a license, license renewal or authorization to sit for an examination based upon a material mistake of fact;

2. Has engaged in the use or employment of dishonesty, fraud, misrepresentation, false promise, false pretense, unethical conduct or unprofessional conduct, as may be determined by the Board, in the performance of the function or duties of an osteopathic physician, including but not limited to the following:

- a. Obtaining or attempting to obtain a fee, charge, tuition or other compensation by fraud, deception or misrepresentation; willfully and continually overcharging or overtreating patients; or charging for visits to the physician's office which did not occur or for services which were not rendered,
- **b.** using intimidation, coercion or deception to obtain or retain a patient or discourage the use of a second opinion or consultation,

- c. willfully <u>performing inappropriate or unnecessary treatment</u>, diagnostic tests or osteopathic medical or surgical services,
- d. delegating professional responsibilities to a person who is not qualified by training, skill, competency, age, experience or licensure to perform them, noting that delegation may only occur within an appropriate doctor/patient relationship, wherein a proper patient record is maintained including, but not limited to, at the minimum, a current history and physical,
- e. misrepresenting that any disease, ailment, or infirmity can be cured by a method, procedure, treatment, medicine or device,

- f. acting in a manner which results in final disciplinary action by any professional society or association or hospital or medical staff of such hospital in this or any other state, whether agreed to voluntarily or not, if the action was in any way related to professional conduct, professional competence, malpractice or any other violation of the Oklahoma Osteopathic Medicine Act,
- **g.** signing a blank prescription form; or dispensing, prescribing, administering or otherwise distributing any drug, controlled substance or other treatment without sufficient examination or the establishment of a physician/patient relationship, or for other than medically accepted therapeutic or experimental or investigational purpose duly authorized by a state or federal agency, or not in good faith to relieve pain and suffering, or not to treat an ailment, physical infirmity or disease, or violating any state or federal law on controlled dangerous substances,

• h. <u>engaging in any sexual activity within a physician/patient</u> relationship,

- i. terminating the care of a patient without adequate notice or without making other arrangements for the continued care of the patient,
- j. <u>failing to furnish a copy of a patient's medical records</u> upon a proper request from the patient or legal agent of the patient or another physician; or failing to comply with any other law relating to medical records,
- **k.** failing to comply with any subpoena issued by the Board,

- 1. <u>violating a probation agreement</u> or order with this Board or any other agency, and
- m. failing to keep complete and accurate records of purchase and disposal of controlled drugs or narcotic drugs;
- 3. Has engaged in gross negligence, gross malpractice or gross incompetence;
- 4. Has engaged in <u>repeated acts</u> of <u>negligence</u>, <u>malpractice</u> or <u>incompetence</u>;
- **5.** Has been <u>finally adjudicated</u> and <u>found guilty</u>, or <u>entered a plea of</u> <u>guilty or nolo contendere</u> in a <u>criminal prosecution</u>, for any offense reasonably related to the qualifications, functions or duties of an osteopathic physician, or for any offense involving moral turpitude, whether or not sentence is imposed, and regardless of the pendency of an appeal;

- 6. Has had the authority to engage in the activities regulated by the Board revoked, suspended, restricted, modified or limited, or has been reprimanded, warned or censured, probated or otherwise disciplined by any other state or federal agency whether or not voluntarily agreed to by the physician including, but not limited to, the denial of licensure, surrender of the license, permit or authority, allowing the license, permit or authority to expire or lapse, or discontinuing or limiting the practice of osteopathic medicine pending disposition of a complaint or completion of an investigation;
- 7. Has violated, or failed to comply with provisions of any act or regulation administered by the Board;

- 8. Is incapable, for medical or psychiatric or any other good cause, of discharging the functions of an osteopathic physician in a manner consistent with the public's health, safety and welfare;
- 9. Has been guilty of advertising by means of knowingly false or deceptive statements;
- 10. Has been guilty of advertising, practicing, or attempting to practice under a name other than one's own;
- 11. Has violated or refused to comply with a lawful order of the Board;
- 12. <u>Has been guilty of habitual drunkenness</u>, or <u>habitual addiction</u> to the use of morphine, cocaine or other habit-forming drugs;

• 13. Has been <u>guilty of personal offensive behavior</u>, which would include, but not be limited to obscenity, lewdness, molestation and other acts of moral turpitude; and

• 14. Has been <u>adjudicated</u> to be <u>insane</u>, or <u>incompetent</u>, or admitted to an institution for the treatment of psychiatric disorders.

HOW IS A VERIFIED COMPLAINT FILED?



Case goes to Board's prosecuting attorney to draft a Verified Complaint



Charges (Verified Complaint) are drafted

 \checkmark

Respondent served with Citation, Notice of Hearing and Complaint



WHAT ARE THE <u>CONSEQUENCES</u> OF BOARD ACTION?

- Revocation
- Suspension
- Usually, emergency suspension or surrender of license
- Multi-year probation upon reinstatement

CONSEQUENCES CONT'D

- Competency evaluation (outof-state)
- Prescribing course (out-ofstate)
- Ethics course (out-of-state)
- Long-term treatment (out-ofstate)
- Probation appearances (Board)
- Cost assessment of investigation and Board Hearing

CONSEQUENCES CONT'D

- Action to National Practitioner Databank
- Action to FSMB
- Action on Board website
- Action to OBN loss of narcotic registration
- Action to DEA loss of narcotic registration
- Possible criminal charges
- Show-cause hearings OBN / DEA-in Washington, D.C.

CONSEQUENCES CONT'D

- Legal fees (enormous)
- Loss of provider status insurance
- Loss of hospital privileges
- Loss of specialty board certification
- Substantial personal embarrassment

CATASTROPHIC FINANCIAL LOSSES!

HOW DO I STAY OUT OF TROUBLE WITH THE BOARD, OBN AND DEA?

DOCUMENTATION!

"While the prescribing healthcare professional is obligated to treat pain, he or she must appreciate the importance of complete documentation . . ."

(Pain Medicine News, Special Report, December 2004)

"Curtailing drug abuse and drug diversion can be accomplished without unduly impeding the compassionate use of narcotic analgesics . . ."

(Journal of Medical Licensure and Discipline, Vol 91,No. 2, 2005, David G. Greenberg, MD, MPH)

Screening, Monitoring, and Documentation

RESPONSIBLE PRESCRIBING AND DOCUMENTATION

Documentation (OAC 510:5-9-1)

- Complete H & P
- Pain Assessment
- Physical and psychological function
- History of substance abuse
- Co-existing conditions
- Treatment of Objectives
- Risk/Benefit Discussion
- Other modalities
- PMP Search



HOW – AND WHY – DO DOCTORS GET INTO TROUBLE PRESCRIBING FOR CHRONIC PAIN?

Scammed by 'professional' patients

• Failure to implement adequate screening procedures and office policies

Failure to engage patient monitoring techniques

- Guarding against drug diversion and abuse
- Ignoring aberrant behavior and clinical impairment

Failure to properly document patient charts

- No Pain Management Agreement (MAJOR VIOLATION)
- Inadequate H&P, lab, imaging, other diagnostic indicators
- Treatment plans, assessments, records, referrals, consults

Sometimes considered 'passive mistakes' resulting in non-punitive remedial action as opposed to punitive action (Board Order)

ACCESSIBILITY TO THE OKLAHOMA STATE BOARD OF OSTEOPATHIC EXAMINERS

• Contact the Board by Mail:

OSBOE

4848 N. Lincoln Blvd., Suite 100

Oklahoma City, OK 73105

• Contact the Board's website:

www.osboe.ok.gov

• Contact the Board by telephone:

405.528.8625 (M-F) 8:00 a.m. – 4:30 p.m.

- Contact the Executive Director 24/7 by telephone at 405/543-8877
- Contact the Board by fax:

405.557.0653